

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

FILED  
IN CLERK'S OFFICE  
DISTRICT COURT E.D.N.Y.

JUDITH GOLD,

Plaintiff,

v.

MERCK & COMPANY, INC.,

Defendant.

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APR 21 2008

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Civil Action No.

LONG ISLAND OFFICE

CV 08 1650  
JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL **GARAUFIS, J.**

Plaintiff Judith Gold ("Plaintiff"), by and through her undersigned attorneys, sues  
Defendant Merck & Company, Inc., and alleges as follows:

**MATSUMOTO, M.**

**I. JURISDICTION AND VENUE**

1. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the County of Queens, State of New York and Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.00.

2. Venue is proper within this district and division pursuant to 28 U.S.C. § 1391.

3. This case is subject to MDL 1789.

**PARTIES**

4. At all relevant times, Plaintiff was a resident of Queens County, New York. Plaintiff used Fosamax from approximately 1996 to 2006, until she experienced oral and dental complications, including exposed necrotic bone and surgery to remove necrotic bone.

5. Plaintiff brings this action individually to recover damages, restitution, refunds, and/or for equitable, injunctive and declaratory relief against Defendant.

6. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, White House Station, New Jersey 08889-3400.

7. The Defendant's registered agent is CT Corporation System, and may be served at 111 Eighth Avenue, New York, New York 10011.

8. Defendant was at all times authorized to conduct business in the State of New York.

9. Defendant has regularly transacted business in the State of New York and continues to do so.

10. At all relevant times Defendant, through its agents, servants, employees, and apparent agents, was the designer, manufacturer, marketer, distributor and seller of Fosamax, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Padgett's Disease.

11. Defendant, either directly or through its agents, apparent agents, servants, or employees, at all relevant times sold, marketed, and distributed Fosamax in the State of New York.

12. Defendant placed Fosamax into the stream of the worldwide commerce and interstate commerce in the United States. Defendant knew or should have known the serious side effects of Fosamax at the time that it marketed the drug to the public. Defendant did so without conducting adequate testing to establish the safety of Fosamax before marketing it. Rather, Defendant aggressively marketed Fosamax and promoted its use while downplaying evidence of the risk of a serious side effect — osteonecrosis of the jaws.

## **II. FACTUAL BACKGROUND**

13. In September 1995, the United States Food & Drug Administration ("FDA") approved Defendant's compound Alendronate for various uses, including the treatment of osteoporosis and Paget's disease.

14. Alendronate's brand name is Fosamax. Defendant markets, distributes, and sells Alendronate as Fosamax. Fosamax has been widely promoted by Defendant as effective and safe.

15. Fosamax has been prescribed to millions of patients every year in the United States, and is sold throughout the world. Fosamax is one of Defendant's top selling drugs, averaging more than \$3 billion a year in sales.

16. Fosamax is part of a class of drugs known as bisphosphonates. Bisphosphonates are used in treating bone conditions such as osteoporosis and Padget's disease. Other drugs in this class include Aredia and Zometa, which are used intravenously with cancer patients as chemotherapy and as adjunct chemotherapy.

17. There are two classes of bisphosphonates: the nitrogen containing and the non-nitrogen containing. Fosamax, like Aredia and Zometa, is a nitrogen containing bisphosphonate. The Physician's Desk Reference for Fosamax confirms that the compound contains nitrogen.

18. Because Fosamax contains nitrogen it accumulates in the bone and does not cleave or metabolize. Thus, Fosamax has an extremely long half-life (10 years).

19. Bisphosphonates, including Fosamax, inhibit bone formation, which in turn affects bone turnover and renewal, thus affecting bone re-absorption and remodeling.

20. Because jawbones remodel at a rate of 10 times the rate of other skeletal bones and have a greater uptake of bisphosphonates, bone re-absorption and remodeling is more

significantly affected by the ingestion of Fosamax. Thus, as the demand for remodeling occurs or if trauma, such as tooth removal or deep cleaning, occurs, jawbones can no longer respond by forming new bone and become necrotic. This is called osteonecrosis of the jaws.

21. Osteonecrosis of the jaws is a rare disease. It is disfiguring and disabling. Osteonecrosis of the jaws is a condition characterized by exposed necrotic (dead) bone in the mandible or maxilla. The necrotic bone is non-healing. There is a high incidence of infection, which can lead to osteomyelitis and infected jawbones. The disease process can progress to a point where either necrotic bone detaches from the jaws leading to sequestration of bone or can require sections of the necrotic bone to be surgically removed. Osteonecrosis of the jaws is difficult to treat and is typically irreversible.

22. For years since Defendant began selling, marketing, and distributing Fosamax, physicians and dentists have acknowledged the observed risk of osteonecrosis of the jaws caused by the use of the intravenous bisphosphonates, Aredia and Zometa.

23. Since the late 1990's, medical articles and studies linked the use of the nitrogenous bisphosphonates for chemotherapy with osteonecrosis of the jaws.

24. In November 2003, the FDA's Office of Drug Safety ("ODS") completed a consult regarding osteonecrosis of the jaws associated with the intravenous bisphosphonates. The ODS concluded that there was a safety concern with intravenous bisphosphonates and that labeling should be amended to include that osteonecrosis of the jaws is associated with these medications. Further, there was a need to review oral bisphosphonates like Fosamax, to determine if osteonecrosis of the jaws is a class wide effect.

25. In 2005, several studies were published that confirmed the significance of the disease and confirmed the causal link between osteonecrosis of the jaws and the use of intravenous nitrogenous bisphosphonates.

26. Defendant, knowing that Fosamax was a nitrogen containing bisphosphonate, knew or should have known that Fosamax shared the same risks as Aredia and Zometa, the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study regarding the risk of osteonecrosis of the jaws relative to Fosamax. Further, despite knowledge of this class effect, Defendant failed to warn of the risk of osteonecrosis of the jaws.

27. Since its November 2003 consult, the FDA continued to receive reports of osteonecrosis of the jaws and other dental complications among users of bisphosphonates, including Fosamax. This prompted the FDA's ODS to conduct an epidemiological review of the FDA's adverse events database. The ODS focused on Aredia, Zometa, Actonel, and Fosamax — all nitrogenous bisphosphonates — to determine if osteonecrosis of the jaws was a class wide effect.

28. As a result of the ODS's review, it issued a Post Marketing Safety Review of bisphosphonates in August 2004 concluding that the risk of osteonecrosis of the jaws was not only confined to intravenous bisphosphonate use, but was a class wide event.

29. Based on this finding, the FDA indicated a need for changes to the product labels, including Fosamax's label, to specifically warn about the risk of osteonecrosis of the jaws.

30. Defendants failed to make the necessary changes to Fosamax's product label. Rather than warn the patients and physicians, Defendant continues to intentionally mislead patients, physicians and the public by defending Fosamax and minimizing unfavorable press and findings.

31. Since approving Fosamax, the FDA has admonished Defendant several times for overstating the benefits of Fosamax and minimizing the risks in its marketing materials. Despite these admonishments, Defendant has not changed its pattern of behavior.

32. In fact, rather than evaluating the safety of Fosamax, Defendant sought to extend the use of its product by manufacturing, marketing, selling, and distributing Fosamax-D. Defendants also sought to extend the exclusivity period of Fosamax through 2018.

33. Defendant knew or should have known about the significant risks of dental and oral and dental complications, including osteonecrosis of the jaws, caused by the ingestion of Fosamax. Despite this knowledge, Defendant did not adequately or sufficiently warn consumers, including Plaintiff, or the medical community of such risks.

34. As a direct result of Defendant's conduct, Plaintiff was prescribed Fosamax from approximately 1996 to 2006. Plaintiff used Fosamax as prescribed and in a foreseeable manner.

35. As a direct and proximate result of ingesting Fosamax, Plaintiff has been permanently and severely injured. Plaintiff requires and will in the future require ongoing medical and dental care and treatment.

### **III. CAUSES OF ACTION**

#### **COUNT 1: NEGLIGENCE**

36. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

37. Defendant had a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, selling, and/or distributing Fosamax into the stream of commerce. Defendant had a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects and harm.

38. Defendant failed to exercise ordinary care in the design, manufacture, marketing, advertising, testing, quality assurance, quality control, sale and/or distribution of Fosamax into the stream of commerce.

39. Defendant was negligent in the design, marketing, manufacture, testing, advertising, warning, sale and/or distribution of Fosamax in that it:

- a. Failed to use due care in designing Fosamax so as to avoid the oral and dental complications and side effects, including osteonecrosis of the jaws;
- b. Failed to accompany Fosamax with proper warnings regarding all possible side effects associated with the use of Fosamax;
- c. Failed to properly and thoroughly conduct adequate pre-clinical testing of Fosamax before releasing the drug to the market;
- d. Failed to properly and thoroughly analyze the data resulting from the pre-marketing test of Fosamax;
- e. Failed to conduct sufficient post-market testing and surveillance and/or medical monitoring to determine the safety of Fosamax;
- f. Failed to accompany Fosamax with adequate warnings of the significant and dangerous risks and failed to provide proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- g. Failed to exercise due care when advertising and promoting Fosamax;
- h. Failed to provide adequate training and/or information to health care professionals for appropriate use of Fosamax; and
- i. Failed to warn that the dangers and risks associated with Fosamax could exceed other comparable treatments for osteoporosis.

40. Despite the fact that Defendant knew or should have known that Fosamax caused unreasonable, dangerous side effects which many users would be unable to remedy by any

means, Defendant continued and still continues to market Fosamax to consumers, including Plaintiff, when there were safer alternative methods for the treatment of osteoporosis.

41. Defendant knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

42. Likewise, Defendant was negligent in seeking approval, marketing and selling Fosamax-D, given Defendant's knowledge of the dangers associated with Fosamax, nitrogenous bisphosphonates.

43. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

44. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and osteonecrosis of the jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

**COUNT 2: STRICT LIABILITY — DESIGN DEFECT**

45. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

46. At all times material to this lawsuit, Defendant manufactured Fosamax.

47. At all times material to this lawsuit, Defendant was engaged in the business of distributing and selling Fosamax.

48. Defendant sold the Fosamax, which was ingested by Plaintiff, as alleged in this Complaint.

49. Plaintiff ingested Fosamax which was expected to reach the user without substantial change in the condition in which it was sold.

50. Plaintiff ingested Fosamax which reached her without substantial change in the condition in which it was sold.

51. Plaintiff was a person who would reasonably be expected to use Fosamax.

52. Fosamax was defective and, because of its defects, was unreasonably dangerous to persons who might reasonably be expected to require its use. In addition, this drug was dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff, and any benefit of this drug was far outweighed by the serious and undisclosed risks of its use.

53. The Fosamax manufactured and/or supplied by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with its design or formulation.

54. Despite the fact that Defendant knew or should have known that Fosamax caused unreasonable and dangerous side effects, which users would be unable to avoid by any means,

they continued to promote and market Fosamax when there existed safer and more effective alternative drug products.

55. Fosamax was defective at the time it was distributed by the Defendants or left its control.

56. The defects in the Fosamax ingested by Plaintiff were a direct and proximate cause of the injuries and damages sustained by Plaintiff as set forth in this Complaint.

57. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and osteonecrosis of the jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

**COUNT 3: STRICT LIABILITY — MARKETING DEFECT — FAILURE TO WARN**

58. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows:

59. At all times material to this lawsuit, Defendants manufactured Fosamax.

60. At all times material to this lawsuit, Defendants were engaged in the business of distributing and selling Fosamax.

61. Defendants sold the Fosamax, which was ingested by Plaintiff, as alleged in this Complaint.

62. Plaintiff ingested Fosamax which was expected to reach the user without substantial change in the condition in which it was sold.

63. Plaintiff ingested Fosamax which reached her without substantial change in the condition in which it was sold.

64. Plaintiff was a person who would reasonably be expected to use Fosamax.

65. Fosamax is unreasonably dangerous, even when used for its intended purpose.

66. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks of Fosamax.

67. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to Plaintiff or her physician.

68. Defendant had a continuing duty to warn consumers and physicians, including Plaintiff and Plaintiff's physicians, of the risks and dangers associated with Fosamax.

69. Defendant marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Fosamax, to health care providers empowered to prescribe and dispense Fosamax to consumers, including Plaintiff, without adequate warning and misled the medical community about the risk/benefit balance of Fosamax, which resulted in injury to Plaintiff.

70. Despite the fact that Defendant knew or should have known that Fosamax caused unreasonable and dangerous side effects, which users would be unable to avoid by any means, they continued to promote and market Fosamax when there existed safer and more effective alternative drug products.

71. Defendant knew or should have known that consumers, including Plaintiff, would foreseeably and needlessly suffer injury as a result of the Defendant's failure to warn.

72. Defendant failed to provide timely and adequate warnings to physicians, distributors, and consumers, including Plaintiff and her physician, in the following ways:

- a. Failed to include adequate warnings with the medications that would alert Plaintiff and Plaintiff's physician to the dangerous risks of Fosamax;
- b. Failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, osteonecrosis of the jaws; and
- c. Continued to aggressively promote Fosamax, even after Defendant knew or should have known of the risks of injury from this drug.

73. By failing to warn Plaintiff and Plaintiff's physician of the adverse health risks associated with Fosamax, Defendant breached their duty to Plaintiff of reasonable care and safety.

74. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and osteonecrosis of the jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

75. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damage so as to punish Defendant and deter it from similar conduct in the future.

#### **COUNT 4: BREACH OF EXPRESS WARRANTY**

76. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

77. Defendant expressly represented to Plaintiff and other consumers in the medical community that Fosamax was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

78. Fosamax does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

79. At all relevant times Fosamax did not perform as safely as ordinary consumers would expect when used as intended or in a reasonably foreseeable manner.

80. Plaintiff, other consumers, and the medical community relied upon Defendant's express warranties.

81. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and osteonecrosis of the jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses

and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

82. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

#### **COUNT 5: BREACH OF IMPLIED WARRANTY**

83. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

84. Defendant manufactured, distributed, advertised, promoted and sold Fosamax.

85. At all relevant times, Defendant knew of the use for which Fosamax was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

86. Defendant was aware that consumers, including Plaintiff, would use Fosamax for treatment of osteoporosis and for other purposes. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendant to sell Fosamax only if it was indeed of merchantable quality and safe and fit for its intended use.

87. Defendant breached its implied warranty to consumers, including Plaintiff. Fosamax was not of merchantable quality or safe and fit for its intended use.

88. Consumers, including Plaintiff and the medical community, reasonably relied upon Defendant's implied warranty for Fosamax.

89. Fosamax reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

sustained oral and dental complications and osteonecrosis of the jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

91. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

#### **COUNT 6: FRAUDULENT MISREPRESENTATION**

92. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

93. Defendant made fraudulent misrepresentations with respect to Fosamax in the following particulars:

- a. Defendant represented through its labeling, advertising, marketing, materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that Fosamax had been tested and found to be safe and effective for the treatment of pain and inflammation; and
- b. Defendant represented that Fosamax was safer than other alternative medications.

94. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Fosamax to consumers, including Plaintiff, and the medical community.

95. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, would rely upon them.

96. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, the medical community, and to induce and encourage the sale of Fosamax.

97. Plaintiff, Plaintiff's doctors, and others relied upon the representations.

98. Defendant's fraudulent representations evidence its callous, reckless, willful, and depraved indifference to health, safety, and welfare of consumers, including Plaintiff.

99. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and osteonecrosis of the jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

100. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of

consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

#### **COUNT 7: FRAUDULENT CONCEALMENT**

101. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

102. Defendant fraudulently concealed information with respect to Fosamax in the following particulars:

- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that Fosamax was safe and fraudulently withheld and concealed information about the substantial risk of use of Fosamax; and
- b. Defendant represented that Fosamax was safer than other alternative medications and fraudulently concealed information which demonstrated that Fosamax was not safer than alternatives available on the market.

103. Defendant had sole access to material facts concerning the dangers and unreasonableness of Fosamax.

104. The concealment of information by Defendant about the risks of Fosamax was intentional, and the representations made by Defendant were known by Defendant to be false.

105. The concealment of information and the misrepresentations about Fosamax were made by Defendant with the intent that doctors and patients, including Plaintiff, would rely upon them.

106. Plaintiff, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of Fosamax which Defendant concealed from Plaintiff and the medical community.

107. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and osteonecrosis of the jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

108. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

#### **COUNT 8: PUNITIVE DAMAGES**

109. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

110. Defendant has repeatedly engaged in a pattern of conduct of deliberately misleading consumers and the medical community of the risks and benefits associated with Fosamax.

111. Defendant has been repeatedly admonished by the FDA for marketing and promotional materials that were in violation of the Federal Food, Drug, and Cosmetic Act. Since 1995, the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC")

issued several letters to Defendant identifying various misleading marketing and promotional materials.

112. In August of 1997, the DDMAC informed Defendant that its "Compare the Facts" Flashcard was misleading because it failed to present important risk information for Fosamax and lacked a fair balance of the risks and benefits. Further, the Flashcard was misleading because it implied that Fosamax's efficacy was superior to other treatments despite the lack of data. The brochure also overstated the population of women eligible for therapy with Fosamax.

113. The DDMAC informed Defendant of another violation in August of 1997. Defendant was put on notice of several violations regarding a Fosamax brochure, reprint holder, slide presentation and journal ad. The FDA concluded that all of the materials were misleading because the Defendant failed to present important risk factors, failed to present a fair balance presentation of risk information and efficacy, and overstated the efficacy of Fosamax as related to fracture incidence. Overall, the FDA requested Defendant to discontinue the dissemination of the misleading materials.

114. Again in 1999, Defendant was requested to discontinue the use of certain promotional materials for Fosamax because it failed to include risk information or a summary of necessary information related to side effects.

115. In 2000 and 2001, the DDMAC issued yet another admonishment regarding Defendant's Fosamax web site which overstated the potential benefit of Fosamax while down playing the risks and serious adverse effects associated with Fosamax.

116. Despite these repeated admonishments by the FDA, Defendant has engaged in the same pattern of conduct. Defendant continues to mislead the consumers and medical community

by working to defend Fosamax and minimize the risk of osteonecrosis of the jaws in its promotional materials.

117. Defendant has also repeatedly engaged in the pattern of conduct of deliberately avoiding the FDA's recommendations regarding which risks associated with Defendant's drugs should be warned about.

118. In November 2003, the FDA's Office of Drug Safety ("ODS") completed a consult regarding osteonecrosis of the jaws associated with the intravenous bisphosphonates. The ODS concluded that labeling should be amended to include that osteonecrosis of the jaws is associated with these medications. Further, the ODS stated that there was a need to review oral bisphosphonates like Fosamax, to determine if osteonecrosis of the jaws is a class wide effect.

119. After its November 2003 consult, the ODS conducted an epidemiological review of the FDA's adverse events database. The ODS focused on Aredia, Zometa, Actonel, and Fosamax — all nitrogenous bisphosphonates — to determine if osteonecrosis of the jaws was a class wide effect. As a result of this review, the FDA issued a Post Marketing Safety Review of bisphosphonates in August 2004 concluding that the risk of osteonecrosis of the jaws was not only confined to intravenous bisphosphonate use, but was a class wide event. Thus, the FDA indicated a need for changes to the product labels, including Fosamax's label, to specifically warn about the risk of osteonecrosis of the jaws.

120. Despite, the August 2004 FDA's indication to change the Fosamax label and to warn of osteonecrosis of the jaws, Defendant has failed to do so. Rather than warn the patients and physicians, Defendant continues to intentionally mislead patients, physicians and the public by defending Fosamax and minimizing unfavorable press and findings.

121. Defendant's disregard of the FDA's recommendations has not only occurred with its drug Fosamax, but also with its drug Vioxx.

122. In March 2000, Defendant completed a study called VIGOR (Vioxx Gastrointestinal Outcome Research) relating to its prescription Cox-II inhibitor, Vioxx. The VIGOR study showed that Vioxx patients had more than doubled the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug. The study was published in the New England Journal of Medicine.

123. In September 2001, the FDA admonished Defendant to stop misleading consumers and the medical community about Vioxx's effects on the cardiovascular system and minimizing the risks of the drug in its marketing. Like with Fosamax and osteonecrosis of the jaws, Defendant refused to adequately warn consumers and the medical community about the risks of heart attacks and Vioxx.

124. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that Vioxx users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or other non-steroidal drugs. The FDA representative concluded that Vioxx was linked to more than 2,700 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

125. Defendant worked to defend Vioxx, much like it is doing now with Fosamax. On August 26, 2004, Defendant released a press statement which refuted the FDA's analysis and restated Defendant's support for the cardiovascular safety of Vioxx.

126. Despite its defense of Vioxx, one month later, on September 30, 2004, Defendant recalled Vioxx from the market, after having to halt the APPROVe study (Adenomatous Polyp

Prevention on Vioxx). The study was underweighted to evaluate the use of Vioxx for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug users in the APPROVE study.

127. At the same time, Defendant was aware that the FDA, as of August 24, 2004, was advising Defendant to warn about the risk of osteonecrosis of the jaws for its Fosamax patients. Because Defendant knew that its blockbuster drug, Vioxx, was about to be pulled from the market, placing more importance on the \$3 billion plus sales of Fosamax, Defendant deliberately chose not to amend its packaging and labels of Fosamax to include the risk of osteonecrosis of the jaws, fearing that such a warning would result in reduced revenues for its second largest income producer, Fosamax.

128. Defendant's acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and to deter similar conduct in the future.

## V. DAMAGES

129. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

130. As a proximate result of Defendant's acts and omissions, Plaintiff sustained and suffered oral and dental complications, including exposed necrotic bone and surgery to remove the dead bone.

131. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff sustained oral and dental complications and osteonecrosis of the

jaws. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, the diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

132. Additionally, Plaintiff has suffered or will suffer the following damages:

- a. Physical pain and mental anguish in the past;
- b. Physical pain and mental anguish in the future;
- c. Lost earnings in the past;
- d. Loss of earning capacity in the future;
- e. Disfigurement in the past and future;
- f. Physical impairment in the past and future;
- g. Loss of enjoyment of life and diminished physical abilities;
- h. Pain and suffering;
- i. Worry and anxiety;
- j. Medical expenses in the past and future; and
- k. All hedonic damages allowed by law.

133. As stated above, Defendant acted with intent and malice. Plaintiff is entitled to an award of exemplary damages.

**VI. DEMAND FOR JURY TRIAL**

134. Plaintiff requests a trial by jury on all counts.

**VII. PRAYER**

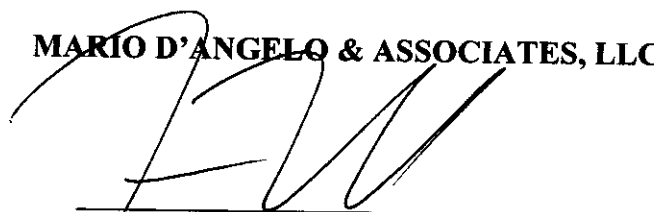
WHEREFORE, Plaintiff demands judgment against Defendant for:

- a. Actual damages; and
- b. Pre-judgment and post-judgment interest as allowed by law in an amount in excess of the jurisdictional limits of this court, plus costs, as well as other equitable and just relief. Additionally, Plaintiff demands judgment against Defendant for exemplary damages.

Dated this 22nd day of April, 2008.

Respectfully submitted,

**MARIO D'ANGELO & ASSOCIATES, LLC**



---

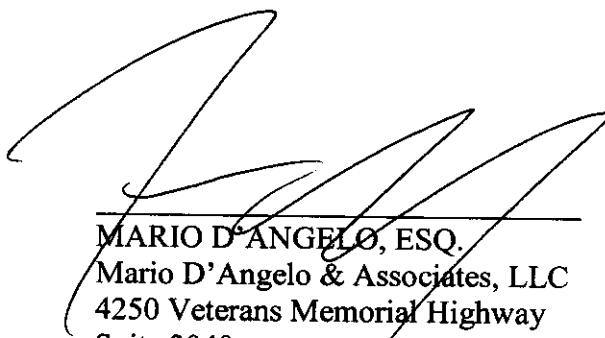
Mario D'Angelo, Esq.  
New York Bar No. 2178044  
4250 Veterans Memorial Highway  
Suite 2040  
Holbrook, NY 11741  
Telephone (713) 621-7944  
Facsimile (713) 621-9638

**COUNSEL FOR PLAINTIFF**

**CERTIFICATION**

I, the undersigned, an attorney duly admitted to practice law in the courts of the State of New York and a partner in the firm of Mario D'Angelo & Associates, LLC, attorneys for the petitioner herein, hereby certify that the statements contained herein are accurate and true to the best of my knowledge under the penalties of perjury.

DATED: Holbrook, New York  
April 22, 2008



MARIO D'ANGELO, ESQ.  
Mario D'Angelo & Associates, LLC  
4250 Veterans Memorial Highway  
Suite 2040  
Holbrook, NY 11741  
Tel: (631) 656-1100  
Fax: (631) 656-1104

FILED

JS 44 (Rev. 12/07)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

APR 21 2008

## I. (a) PLAINTIFFS

JUDITH GOLD

(b) County of Residence of First Listed Plaintiff QUEENS  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Mario D'Angelo & Associates, LLC, 4250 Veterans Memorial Highway, Suite 2040, Holbrook, NY 11741 (631)656-1100

## DEFENDANTS

MERCK &amp; COMPANY, INC.

LONG ISLAND OFFICE

County of Residence of First Listed Defendant  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (Known)  
Unknown

CV 08 1650

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff  
☐ 2 U.S. Government Defendant  
☐ 3 Federal Question (U.S. Government Not a Party)  
☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State ☒ 1 ☐ 2  
Citizen of Another State ☐ 2 ☐ 3  
Citizen or Subject of a Foreign Country ☐ 3 ☐ 3 Foreign Nation ☐ 6 ☐ 6

GARALFIS, J. MATSUMOTO, M.

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	PERSONAL INJURY	PERSONAL INJURY	PROPERTY DAMAGE	LABOR/EMPLOYMENT	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other <b>LABOR/EMPLOYMENT</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>INTELLECTUAL PROPERTY</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>REAL ESTATE TAX SUITS</b> <input type="checkbox"/> 861 HIA (1395f) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes

## V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 USC 1332

Brief description of cause:  
To recover monetary damages for personal injuries sustained as a result of exposure to Fosamax.

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

## DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE MDL 1789

DOCKET NUMBER

DATE

04/22/2008

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_

**ARBITRATION CERTIFICATION**

I, Mario D'Angelo, counsel for Plaintiff, Judith Gold do hereby certify pursuant to the Local Arbitration Rule 83.10 that to the best of my knowledge and belief the damages recoverable in the above captioned civil action exceed the sum of \$150,000 exclusive of interest and costs. Relief other than monetary damages is sought.

---

**DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1**

Identify any parent corporation and any publicly held corporation that owns 10% or more of its stocks:

---

**Please refer to NY-E Division of Business Rule 50.1(d)(2)**

1.) Is the civil action being filed in the Eastern District of New York removed from a New York State court located in Nassau or Suffolk County: NO

2.) If you answered "no" above:

a.) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? NO

b.) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? YES

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County? \_\_\_\_\_

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

---

**I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.**

Yes ✓

No \_\_\_\_\_

**Are you currently the subject of any disciplinary action(s) in this or any other state or federal court?**

Yes \_\_\_\_\_ (If yes, please explain)

No ✓

---

Please provide your E-MAIL Address and bar code below. Your bar code consists of the initials of your first and last name and the last four digits of your social security number or any other four digit number registered by the attorney with the Clerk of Court.

(This information must be provided pursuant to local rule 11.1(b) of the civil rules).

**ATTORNEY BAR CODE:** NY 2178044

**E-MAIL Address:** MDESQ@DANGELOLAW.COM

I consent to the use of electronic filing procedures adopted by the Court in Administrative Order No. 97-12, "In re Electronic Filing Procedures(EFP)", and consent to the electronic service of all papers.

**Signature:** \_\_\_\_\_



UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----X  
JUDITH GOLD,

Plaintiff,

- against-

MERCK & COMPANY, INC.,

Defendant.

-----X

ORDER GOVERNING INITIAL  
CONFERENCE AND NOTICE  
OF MANDATORY  
PARTICIPATION IN  
ELECTRONIC CASE FILING

Civil Action 08CV1650(NGG)

MATSUMOTO, United States Magistrate Judge:

An initial conference will be held in the above-captioned case on August 19, 2008, at 10:00A.M. before Kiyo A. Matsumoto, United States Magistrate Judge, at the United States Courthouse, 225 Cadman Plaza East, Brooklyn, New York. All counsel (and any *pro se* parties) must be present. The parties should check in with Chambers at Room 1227 S in advance of the conference and may be directed to a courtroom. **Counsel for plaintiff(s) is responsible for confirming with each defendant's counsel (or *pro se* defendant) that the necessary participants are aware of this conference.**

Plaintiff shall effect service of process in accordance with Rule 4 of the Federal Rules of Civil Procedure and promptly file the returns of service with the Clerk at least one week prior to the initial conference. Plaintiff's counsel is to notify the undersigned, in writing, at least three business days before the scheduled conference if an answer has not been filed. If not every defendant named in the complaint has appeared and counsel believes that the initial conference

Case 1:08-cv-01880-JFK Document 43 Filed 06/05/2008 Page 2 of 7  
would not be precluded without participation of any such defendant or plaintiff. Counsel should promptly submit a written request for an adjournment, at least forty eight (48) hours before the scheduled conference, explaining the reasons for adjournment and the status of service and joinder, and serve a copy on all defendants.

**No request for adjournment will be considered unless made in writing at least forty-eight (48) hours prior to the scheduled conference and only after the parties have consulted with each other and have agreed on several alternate dates.** The party seeking the adjournment shall first file the adjournment request by Electronic Case Filing (ECF), explained below, and may thereafter transmit such adjournment request to Chambers by facsimile at (718) 613-2185. Faxed submissions should not also be mailed.<sup>1</sup>

**At least two business days prior to the initial conference, the parties shall discuss the matters specified in Federal Rule of Civil Procedure 26(f) and complete the attached Questionnaire.** No written report or discovery plan specified by Rule 26(f) need be filed via ECF, but the completed Questionnaire shall be brought to the conference. At least two business days prior to the Rule 26(f) discussion between the parties, the parties shall exchange the mandatory initial disclosures required by Rule 26(a)(1). If plaintiff(s) seek(s) damages for personal injuries allegedly caused by defendant(s), plaintiff(s) must provide signed authorizations for releases of all pertinent records from medical service providers, employers and all other sources with information relating to damages.

---

1

The parties shall also discuss (1) the scope of anticipated electronic discovery, the preservation of electronically stored data, and the cost of locating, maintaining and producing the data, and (2) whether any party will rely upon expert testimony, and if so, whether counsel are able to reach an agreement on how material exchanged between counsel and any expert witness will be treated, and in particular, whether draft expert reports and written electronic communications between expert witnesses and counsel will be retained.

At the initial conference, counsel must be **fully prepared** to discuss any issue regarding this case, including personal and subject matter jurisdiction, venue, schedules for pretrial matters, potential discovery disputes, insurance coverage and settlement. If this case is referred to Court-Annexed Arbitration before the conference, the parties may request in writing either to cancel the initial conference or to attend the conference by telephone, provided they make the arrangements for a conference call.

**By Administrative Order 2004-08, dated June 22, 2004, beginning on August 2, 2004, ECF is mandatory for all civil cases, other than *pro se* cases, and for all criminal cases. All counsel shall register for ECF in this case.** There is no charge to participate. ECF enables both the Court and litigants immediately to file, serve and receive documents electronically, including pleadings, motions, correspondence and orders. Any document filed via ECF is deemed served on all other parties required to participate in ECF and all counsel of record will receive a notice by email of such filing. It is the responsibility of the parties to regularly monitor the status of their cases to avoid missing deadlines and court appearances.

Requests by attorneys for an exemption to the mandatory ECF policy must be submitted to the undersigned magistrate judge within two weeks of the date of this Order, and

must set forth good cause/hardship reasons which state the specific technological reason why counsel is unable to participate in ECF. Before seeking a hardship exemption, attorneys must participate in the training program or otherwise seek assistance from the Clerk's Office. A user's manual is available through the Clerk's Office, or at the Court's website at <http://www.nyed.uscourts.gov>. Free training can be arranged for attorneys and their staff at any of the Eastern District courthouses.

**Counsel of record who do not seek a hardship exemption to ECF must register for ECF within one week of the date of this Order.** For counsel's convenience, the registration form is attached. If there are other attorneys in the firm who will also be working on this case, such attorneys should promptly file a notice of appearance and register for ECF in this case so that they may receive ECF notices.

SO ORDERED.

Dated: Brooklyn, New York  
4/25/2008.

\_\_\_\_\_/s/  
KIYO A. MATSUMOTO  
UNITED STATES MAGISTRATE JUDGE  
(718) 613-2180

**INITIAL CONFERENCE QUESTIONNAIRE**

1. If not yet made, date for completion of automatic disclosures required by Rule 26(a) of the Fed. R. Civ. P.: \_\_\_\_\_ or  
Proposed changes in timing, form or requirements for disclosure: \_\_\_\_\_
2. If additional interrogatories beyond the 25 permitted under the Rule 26 are needed, the total number by: plaintiff(s) \_\_\_\_\_ and defendant(s) \_\_\_\_\_

Case 1:08-cv-01880-JFK Document 4-3 Filed 06/05/2008 Page 5 of 7

3. Maximum number of requests for admission by: Plaintiff(s) \_\_\_\_\_ and defendant(s) \_\_\_\_\_

4. Number of depositions by plaintiff(s) of: parties \_\_\_\_\_ non-parties \_\_\_\_\_

5. Number of depositions by defendant(s) of: parties \_\_\_\_\_ non-parties \_\_\_\_\_

6. Maximum length of each deposition if longer than 7 hours \_\_\_\_\_ non-party \_\_\_\_\_

7. Date for completion of factual discovery: \_\_\_\_\_

8. Number of expert witnesses of plaintiff(s): \_\_\_\_\_ medical \_\_\_\_\_ non-medical

Date for expert report(s): \_\_\_\_\_

9. Number of expert witnesses of defendant(s): \_\_\_\_\_ medical \_\_\_\_\_ non-medical

Date for expert report(s): \_\_\_\_\_

10. Dates for completion of expert discovery: \_\_\_\_\_

11. Time for amendment of the pleadings by plaintiff(s) \_\_\_\_\_ or by defendant(s) \_\_\_\_\_

12. Number of proposed additional parties to be joined by plaintiff(s) \_\_\_\_\_ and defendant(s) \_\_\_\_\_ and time for completion of joinder: \_\_\_\_\_

13. Types of contemplated dispositive motions: \_\_\_\_\_

a. Dates for filing contemplated dispositive motions: \_\_\_\_\_

14. Have counsel reached any agreements regarding electronic disclosure of communications with experts? If so, describe at the initial conference.

15. The parties are advised that they may consent to trial, including a jury trial, before a Magistrate Judge pursuant to 28 U.S.C. § 636(c). They should be prepared to advise the Court whether they consent upon the conclusion of discovery.

United States District Court for the Eastern District of New York

**ECF**

**Registration Form - Page 1**

(<http://www.nyed.uscourts.gov>)

**Person Information:**

<b>Last Name:</b>	<b>Generation</b> (i.e. Jr., Sr., II, III):
<b>First Name:</b>	<b>Middle Name:</b>
<b>Title</b> (i.e. attorney):	<b>Date of Birth:</b>
<b>Last Four Digits Of Your Social Security Number:</b>	
<b>Are you admitted to the bar of the EDNY and, if so, are you a member in good standing?</b> _____ Yes _____ No	

**Office Information:**

<b>Office:</b>		
<b>Address 1:</b>		
<b>Address 2:</b>		
<b>Address 3:</b>		
<b>City:</b>	<b>State:</b>	<b>Zip Code:</b>
<b>County:</b>	<b>Country:</b>	<b>Telephone No: ( )</b>

**User Information:**

<b>Law Firm's Email Address:</b>
<b>Individual's Email Address:</b>
<b>Telephone Number:</b> ( )
<b>Fax:</b> ( )

United States District Court  
Eastern District of New York

## ECF Registration - Page 2

**By submitting this form the undersigned agrees to abide by the following rules:**

1. This System is for those cases designated by the Court for electronic filing. Use the login and password the Court issues *to electronically file* documents. Use your firm's Pacer login and password *to view* docket sheets or *to view* electronically filed documents.

2. Documents must be submitted electronically only in Portable Document Format (**PDF**).
3. The combination of user identification and password will serve as the signature of the attorney / participant filing the documents. Individuals must protect the security of their passwords and immediately notify the Court if they suspect that their password has been compromised.

---

**Applicant's Signature**

Dated: \_\_\_\_\_

**Return your completed form by mail, fax or e-mail to one (1) of the persons listed below:**

Ms. Evelyn Levine  
Training Specialist  
225 Cadman Plaza East, Room 105  
Brooklyn, New York 11201  
Telephone No.: (718) 613-2312  
Email: [Evelyn\\_Levine@nyed.uscourts.gov](mailto:Evelyn_Levine@nyed.uscourts.gov)

Ms. Carol McMahon  
Administrative Supervisor  
United States Federal Courthouse  
100 Federal Plaza  
Central Islip, New York 11722-4438  
Telephone No.: (631) 712-6031  
Fax: (631) 712-6043  
Email:  
[Carol McMahon@nyed.uscourts.gov](mailto:Carol McMahon@nyed.uscourts.gov)

158284 230x 35.00  
United States District CourtAttorney Mario D'Angelo & Associates  
County of Eastern District of New York

Judith Gold

Petitioner  
Plaintiff(s),

Index# 1650/08

-against-

AFFIDAVIT OF SERVICE

Merck &amp; Company, Inc.,

Respondent  
Defendant(s).

STATE OF NEW YORK: COUNTY OF KINGS ss:

Harry Torres

BEING DULY SWORN DEPOSES AND SAYS DEPONENT IS NOT A PARTY TO

THIS ACTION AND IS OVER THE AGE OF EIGHTEEN YEARS AND RESIDES IN THE STATE OF NEW YORK.

That on 04/30/08 at 10:39am at 111 Eighth Avenue 13th Floor New York, NY 10011  
deponent served the within Summons In A Civil Action & Complaint and Demand for Jury  
Trial and Civil Cover Sheeton MERCK & COMPANY, INC. C/O CT CORP. ,  
therein named.

INDIVIDUAL

A.

by delivering a true copy of each to said defendants personally: deponent knew the person so served to be the person described as said defendant therein. (S)He identified (her) himself as such.

CORPORATION/BUSINESS

B. XXXX

a (domestic)(foreign)corporation/business by delivering thereat a true copy of each to Eleana Bou

Personally, deponent knew said corporation/business so served to be the corporation/business described in said summons as said defendant and knew said individual to be Process Specialist/Auth.to accept thereof.

SUITABLE AGE PERSON

C.

by delivering thereat a true copy(ies) of each to a person of suitable age and discretion. Said premises is defendants (actual place of business)(dwelling house)(usual place of abode) within the state. (S)He identified (her)himself as of defendant.

AFFIXING TO DOOR, ETC.

D.

by affixing a true copy(ies) of each to the door of said premises, which is defendants (actual place of business)(dwelling house)(usual place of abode) within the state. Deponent was unable, with due diligence, to find defendant, a person of suitable age and discretion or a work address thereat, having called there on

MAILING USE WITH  
C. & D.

Deponent also mailed a copy(ies) of same post paid by first class mail properly addressed to defendant(s) at the aforementioned address in an envelope marked "personal &amp; confidential" and not indicating that the communication was from an attorney or concerned an action against the defendant(s) and deposited said envelope in a post office official depository under exclusive care and custody of the United States Postal Service within New York State on

Deponent further states that he describes the person actually served as follows

Sex	Skin Color	Hair Color	Age (Approx)	Height (Approx)	Weight (Approx)
female	white	blond	45	5'4	120

MILITARY SERVICE

Above person was asked whether the defendant(s) was(were) in the military service of the State of New York or the United States and received a negative reply. Upon information and belief based upon the conversation and observation as aforesaid deponent avers that the defendant(s) is(are) not in the military service of the State of New York or the United States as that term is defined in the statutes of the State of New York or the Federal Soldiers and Sailors Civil Relief Act.

USE IN NYC CIVIL CT.

The language required by NYCRR (e), (f) &amp; (h) was set forth on the face of the said summons(es).

SUPREME COURT ACTION

Papers so served were properly endorsed with the index number and date of filing.

X

Sworn before me on 05/01/08

NEIL J. SCHRAGER  
Notary Public State of New York  
NO. 21-498776  
Qualified in Kings County  
Commission Expires July 29, 2009

LICENSE NO. 0915257  
Harry Torres

on  
MULTIDISTRICT LITIGATION

**CHAIRMAN:**  
Judge John G. Heyburn II  
United States District Court  
Western District of Kentucky

**MEMBERS:**  
Judge D. Lowell Jensen  
United States District Court  
Northern District of California

Judge J. Frederick Motz  
United States District Court  
District of Maryland

Judge Robert L. Miller, Jr.  
United States District Court  
Northern District of Indiana

Judge Kathryn H. Vratil  
United States District Court  
District of Kansas

Judge David R. Hansen  
United States Court of Appeals  
Eighth Circuit

Judge Anthony J. Scirica  
United States Court of Appeals  
Third Circuit

**DIRECT REPLY TO:**

Jeffery N. Lüthi  
Clerk of the Panel  
One Columbus Circle, NE  
Thurgood Marshall Federal  
Judiciary Building  
Room G-255, North Lobby  
Washington, D.C. 20002

Telephone: [202] 502-2800  
Fax: [202] 502-2888  
<http://www.jpml.uscourts.gov>

May 21, 2008

J. Michael McMahon, Clerk  
Daniel Patrick Moynihan U.S. Courthouse  
500 Pearl Street  
New York, NY 10007-1312

08 CV 1650  
(NCA)

Re: MDL No. 1789 -- IN RE: Fosamax Products Liability Litigation

(See Attached CTO-55)

Dear Mr. McMahon:

I am enclosing a certified copy and one additional copy of a conditional transfer order filed by the Panel in the above-captioned matter on May 5, 2008. As stipulated in Rule 7.4(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), transmittal of the order has been stayed 15 days to give any party an opportunity to oppose the transfer. The 15-day period has now elapsed, no opposition was received, and the order is directed to you for filing.

The Panel's governing statute, 28 U.S.C. §1407, requires that the transferee clerk "...transmit a certified copy of the Panel's order to transfer to the clerk of the district court from which the action is being transferred."

A list of involved counsel is attached.

Very truly,

Jeffery N. Lüthi  
Clerk of the Panel

By Dana R. Stewart  
Deputy Clerk

Attachment

cc: Transferee Judge: Judge John F. Keenan  
Transferor Judges: Judge Morrison C. England, Jr.; Judge Nicholas G. Garaufis  
Transferor Clerks: Jack L. Wagner; Robert C. Heinemann

Inasmuch as no objection is pending at this time, the stay is lifted.

MAY 21 2008

CLERK'S OFFICE  
JUDICIAL PANEL ON  
MULTIDISTRICT LITIGATION

MAY - 5 2008

FILED  
CLERK'S OFFICE

UNITED STATES JUDICIAL PANEL  
on  
MULTIDISTRICT LITIGATION

**IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION**

Leonore Andrade v. Merck & Co., Inc., )  
E.D. California, C.A. No. 2:08-675 )  
Judith Gold v. Merck & Co., Inc., )  
E.D. New York, C.A. No. 1:08-1650 )

MDL No. 1789

**CONDITIONAL TRANSFER ORDER (CTO-55)**

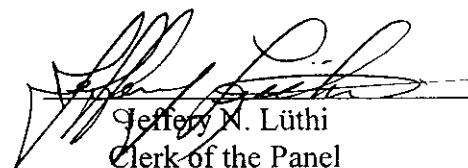
On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 123 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

  
Jeffrey M. Lüthi  
Clerk of the Panel

**IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION**

MDL No. 1789

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Inasmuch as no objection is pending at this time, the stay is lifted.

MAY 21 2008

CLERK'S OFFICE  
JUDICIAL PANEL ON  
MULTIDISTRICT LITIGATION

JUDGE KEENAN

MAY - 5 2008

FILED  
CLERK'S OFFICE

4880

08 CV  
UNITED STATES JUDICIAL PANEL  
on  
MULTIDISTRICT LITIGATION

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION

Leonore Andrade v. Merck & Co., Inc., )  
E.D. California, C.A. No. 2:08-675 )  
Judith Gold v. Merck & Co., Inc., )  
E.D. New York, C.A. No. 1:08-1650 )

MDL No. 1789

FLD  
SD of NY  
5/27/08

CONDITIONAL TRANSFER ORDER (CTO-55)

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A CERTIFIED TRUE COPY

MAY 21 2008

ATTEST  
FOR THE JUDICIAL PANEL ON  
MULTIDISTRICT LITIGATION

FOR THE PANEL:

Jeffery M. Lüthi  
Clerk of the Panel

A CERTIFIED COPY  
J. MICHAEL McMAHON

CLERK

BY

DEPUTY CLERK

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UNITED STATES DISTRICT COURT  
Southern District of New York  
Office of the Clerk  
500 Pearl Street  
New York, N.Y. 10007  
(212)805-0136

**FILED**  
IN CLERK'S OFFICE  
U.S. DISTRICT COURT, E.D.N.Y.  
★ JUN 02 2008 ★  
**BROOKLYN OFFICE**

J. Michael McMahon  
Clerk

USDC ED OF NEW YORK

DATE: 5/27/08

In Re: FOSAMAX

MDL 1789

Your Docket #

S.D. OF N.Y.

1:08-1650

08 CV 4880

Dear Sir:

Enclosed is a certified copy of the order of the Judicial Panel on Multidistrict Litigation, transferring the above entitled action presently pending in your court, to the Southern District of New York and assigned to Judge KEENAN for coordinated or consolidated pretrial processing pursuant to 28 USC 1407.

Please return the copy of this letter when transmitting YOUR FILE and a CERTIFIED COPY OF THE DOCKET SHEET.

Sincerely,  
J.Michael McMahon

By:  
MDL Unit  
(212) 805-0646